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Application. No.: 09/914,088

Docket No. B45172

# **REMARKS**

Applicants have cancelled claim 43, added new claims 84-86, and amended the pending claims 42, 51, 52, and 58-67 in the hope of bringing the claims into conformance with current practices in this art. The amendments are fully supported by the specification. No new matter is added.

# **OBJECTIONS**

At page 2, numbered paragraphs 5 and 6 of the Office Action, Claims 42, 58, and 60-62 stand objected to for reciting non-elected embodiments. In addition, Claims 58-60 are objected to because they are dependent on non-elected claims 44-57. Applicants amended these claims to depend on the elected embodiment P1 (SEQ ID NO. 1) and no longer dependent on Claims 44-57.

At page 3, numbered paragraphs 7 of the Office Action, Claims 51, 52, 59, 60, 61, 62, and 64-67 stand objected to because "A" should have been "The" in dependant claims. Applicants amended Claims 51, 52, 59, 61, and 62 to replace "A" with "The". However, the Applicants respectfully assert that Claims 60 and 64-67 correctly begin with "A". Applicants believe they have clarified any potential objection by amending "...a peptide..." to "...the peptide..." in Claim 60 and amending "...an immunogenic..." to "...the immunogenic..." in Claims 63-67.

The Applicants respectfully submit that in view of the forgoing remarks and the claims as amended, the Applicants have overcome the Examiner's objections and the objections should be withdrawn.

# REJECTIONS UNDER 35 U.S.C. §112, FIRST PARAGRAPH

At pages 3 and 6, numbered paragraphs 9 and 10 of the Office Action, Claims 42, 51-52, and 58-67 are rejected under 35 U.S.C. 112, first paragraph, because the specification lacks enablement and written description.

Applicants assert that the rejections are now moot because of the amendments made to the present claims. Specifically, Claim 1 covers a peptide comprising a region of P1 (SEQ ID NO. 1), in which the peptide must be less than 100 amino acids (support for this amendment is found on page 14, line 10 of the specification). It is believed that none of the prior art disclose such peptides, nor a possible use for these peptides, and this claim is novel and inventive.

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The term "mimotope" is very well known and has a specific meaning that is clear to a man skilled in the art, and is fully defined on pages 5 & 6 of the present specification. A mimotope is a 3D structure that mimics an epitope; for the artisan, identifying such mimics is a matter of using straightforward, well-documented methods, some of which have been highlighted on page 6 of the specification.

The Applicants respectfully submit that in view of the forgoing remarks and the claims as amended, the Applicants have overcome the Examiner's rejections and the rejections should be withdrawn.

# REJECTIONS UNDER 35 U.S.C. §112, SECOND PARAGRAPH

At pages 9, numbered paragraph 12 of the Office Action, Claims 58, 59, 61, 63, 64, and 66 are rejected under 35 U.S.C. 112, second paragraph, because the claims are allegedly indefinite regarding the term "immunogen" and the Examiner suggests that an immunogen does not have a carrier.

The term "immunogen" is very well known and has a specific meaning that is clear to a skilled artisan. For example, according to William R. Clark, The Experimental Foundations of Modern Immunology 440 (2d ed. 1983)(attached herein), an immunogen is defined as "[a] substance capable of provoking an immune response." (emphasis added). Accordingly, Applicants' use of "immunogen", and now "immunogenic composition" clearly indicates that the scope of the claim may include a carrier molecule in amended claim 58.

The Applicants respectfully submit that in view of the forgoing remarks and the claims as amended, the Applicants have overcome the Examiner's rejections and the rejections should be withdrawn.

# REJECTIONS UNDER 35 U.S.C. §102(b) and 103(a)

Applicants have amended Claim 42 to read on a peptide comprising a region of P1, in which the peptide must be less than 100 amino acids (support for this amendment is found on page 14, line 10 of the specification). It is believed that none of the prior art disclose such peptides, nor a possible use for these peptides, and this claim is novel and inventive. Therefore, these rejections are moot.

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The Applicants reserve the right to prosecute, in one or more patent applications, the claims to non-elected inventions, the claims as originally filed, and any other claims supported by the specification. The Applicants thank the Examiner for the Office Action and believe this response to be a full and complete response to such Office Action. Accordingly, favorable reconsideration and allowance of the pending and new claims is earnestly solicited. If it would expedite prosecution of this application, the Examiner is invited to confer with the Applicants' undersigned agent.

Respectfully submitted,

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Immunity In the general sense, refers simply to resistance to extraneous, nonself (foreign) matter. As used by contemporary scientists, refers specifically to those mechanisms of resistance involving the immune system.

Immunogen A substance capable of provoking an immune response. All immunogens are antigens (q.v.) but not all antigens are necessarily immunogens (most haptens, for example).

Immunoglobulin A globular serum glycoprotein with antibody activity. All immunoglobulins are variants of the basic H<sub>2</sub>L<sub>2</sub> tetrapeptide structure.

**Induration** The process of becoming hardened. During a cutaneous delayed hypersensitivity reaction, the skin becomes hardened to the touch in the area of the reaction.

Innate immunity The repertoire of defenses, both immunological and nonimmunological, that exist prior to and independently of exposure to specific environmental antigens.

Interferon A group of mostly low molecular weight, acid stable proteins secreted by virusinfected cells that can protect noninfected cells from virus.

In vitro Literally "in glass." Used to refer to experiments involving living cells or tissues carried out outside the body.

In vivo Refers to experiments or procedures carried out in a living animal.

**Isotype** A product of a gene, some form of which is carried by and expressed in each member of the species. For example, the  $\gamma_1$  gene is carried by each human, although the particular allele of  $\gamma_1$  that is carried can differ among individuals.

**K cells** Also called null cells. Nonphagocytic cells of unknown lineage, similar to lymphocytes but with neither T nor B cell surface markers. K (for "killer") cells can destroy antibody coated target cells by ADCMC (q.v.).

Kinins Peptides released during anaphylaxis that induce contraction of smooth muscle and dilation of blood vessels.

LD antigens (also Lad) Cell surface antigens that provoke a proliferative response in allogeneic T cells.

LDCMC Lectin-dependent cell-mediated cytotoxicity. See CMC.

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LPC Large pyrininophilic cell(s). Lymphoid cells in a blastoid state with abundant pyrinine-staining material (RNA) in the cytoplasm. Used mostly to describe T cells activated in an MLC.

LPS Lipopolysaccharide. A bacterial endotoxin, usually obtained from *E. coli*, capable of activating B cells in an antigen-independent fashion.

**Lectins** A group of plant-derived proteins capable of binding to the surfaces of animal cells. (See Con A, PHA.)

Leukocyte Literally "white cell." A general term formerly used to refer to any cell found in the blood that was not of the erythroid series. No longer particularly useful since the extensive functional and morphological categorization of white blood cells.

Local immunity Immunity that develops in a local site independent of the network of lymph glands and ducts throughout the body. Production of IgA antibodies to bacterial antigens in the gut is an example of local immunity.